REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 11-13 and 15-19 are currently under consideration. Claim 1 has been amended to depend from claim 11. Support for the amendment to claim 1 can be found, for example, in the paragraph beginning on page 4, line 18, and in Example 4 of the specification.

No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. § 112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that these amendments should not give rise to any estoppel, as they are not narrowing amendments.

II. THE CLAIM OBJECTIONS ARE OVERCOME

Claims 11, 12, and 15-17 are objected for being drawn in part to non-elected inventions. This objection is traversed.

The OFFICE ACTION WITH RESTRICTION REQUIREMENT, mailed on June 16, 2006, required Applicants to elect an anti-apoptotic protein and stated that the election would not be regarded as a species election. The bcl-2 protein was elected in response.

Applicants assert that the election of the anti-apoptic protein should be regarded as an election of species because claim 11 is a linking claim. Claim 11 clearly links the invention of Group II, which is directed to untransformed, immortalized avian cells containing nucleic acid molecules encoding an anti-apoptotic protein. Under MPEP § 809, claim 11 is a "genus claim linking species claims," wherein the genus is anti-apoptotic proteins and the species are, inter alia, the proteins recited in claims 13 and 14.

Even if claim 11 is not regarded as a linking claim, it should at the very least be considered a generic claim. According to MPEP § 806.04(d), a generic claim should require no material element additional to those required by the species claims, and each of the species claims must require all the limitations of the generic claim. In this case, claim 11 does not require any material element in addition to the elements required by species claims 13 and 14, and species claims 13 and 14 require all limitations of claim 11. The requirement to restrict the present invention to one embodiment, i.e., bcl-2 protein, is unduly limiting and improper. Moreover, Applicants point out that it is not the anti-apoptotic protein, per se, that is inventive. Rather, it is the use of an anti-apoptotic gene in creating an immortalized avian cell line. Therefore, election of the bcl-2 protein should be considered an election of species.

Upon allowance of the Group II product claims, Applicants request rejoinder under MPEP § 821.04 of method claims 1-10 and 27-33, which depend from and therefore include all the limitations of claim 11.

Applicants also assert that the claims of Groups III and IV are not separate and distinct from elected Group II, and should therefore be included in the claims under consideration by the Examiner. Groups II and III are not independent or distinct, as the only difference between claims 11 (Group II) and 20 (Group III) is that claim 20 presents an additional limitation to claim 11. Claim 20 discloses the cell of claim 11 further containing a heterologous nucleotide sequence; the subject matter of claim 11 necessarily encompasses the subject matter of claim 20, but is narrower in scope. Notably, claim 11 uses open language, as the recitation of the term "contains" indicates that the untransformed, immortalized avian cells can have components in addition to the claimed nucleic acid molecule encoding an anti-apoptotic protein. These additional components can be, for example, a heterologous nucleotide as disclosed in claim 20. Consequently, claim 20 literally falls within the scope of a claim 11, and cannot be said to be independent or distinct. The restriction between Groups II and III is therefore improper and should not be maintained.

Likewise, the only difference between claims 11 (Group II) and 24 (Group IV) is that claim 24 discloses a limitation to claim 11, wherein that the cell of claim 11 is infected with a virus. Claim 24 only narrows the scope of elected claim 11, and certainly does not render it independent or distinct from claim 11. As discussed, the open language in claim 11 would indicate that the untransformed, immortalized avian cells can include additional components,

such as the virus described in claim 24. Thus, the restriction between Groups II and IV is also improper and should not be maintained.

Accordingly, reconsideration and withdrawal of the objection and redrawing of the restriction requirement to include claims 20-26 are requested. Applicants would greatly appreciate the Examiner's assistance in avoiding the time and expense of filing a petition on this issue.

III. THE DOUBLE-PATENTING REJECTION IS OVERCOME

Claims 11-13 and 15-19 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-5 of U.S. Patent No. 6,255,108 ("the '108 patent").

In the interest of advancing prosecution and placing the application in condition for allowance, a Terminal Disclaimer to the '108 patent is enclosed. Consequently, reconsideration and withdrawal of the double patenting rejection with respect to the '108 patent are respectfully requested.

Claims 12 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 11, 15-17, and 19 of copending application U.S.S.N. 11/031,417 ("the '417 application").

The issue of whether there is double patenting is contingent upon whether the claims of the current application and of the '417 application are allowed. Applicants request that the double patenting rejection be held in abeyance until agreement is reached as to allowable subject matter in both applications.

IV. THE REJECTION UNDER 35 U.S.C. § 103(a) IS OVERCOME

Claims 11-13 and 15-19 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Evan (WO 93/20200) and Givol et al. (Cell Growth Differ 5: 419-429, 1994; "Givol"). The rejection is respectfully traversed.

The Office Action alleges that Evans relates to cell and cell lines comprising a bcl-2 gene wherein said gene is inserted into a vector, and said vector can be integrated and used with host cells from any multicellular organism. Givol relates to chicken embryo fibroblasts containing a

retroviral vector encoding bcl-2. According to the Office Action, it would have been obvious to utilize chicken embryo fibroblasts as the host cells for the vector disclosed by Evan.

The issue under §103 is whether the PTO has stated a case of prima facie obviousness. "The PTO has the burden under §103 to establish a prima facie case of obviousness." In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To satisfy this burden, the PTO must meet the criteria set out in M.P.E.P. §706.02(j):

> ...three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

In consideration of the above background, Applicants contend that the Patent Office has failed to meet its burden of making a prima facie case of obviousness. The Office has failed to show that the cited references disclose each and every element of the claimed invention. The Office has also failed to demonstrate how the references provide sufficient teachings or motivation to be combined with knowledge available to one skilled in the art, or with each other, in order to arrive at the claimed invention. Further, the Patent Office has failed to show that there is a reasonable expectation of success that the combination of the references will arrive at the claimed invention.

Firstly, Evan does not teach or suggest cells that are untransformed and immortalized. The Examiner is reminded that the term "untransformed" is defined in the specification as being absent of cancer cell-like properties. This definition is supported throughout the specification, for instance, on page 1, lines 9-22, and in Examples 1 and 3. Evan mentions using cells that are immortalized and derived from tumours, and presents the hybridoma as an exemplary cell (page 24, lines 23-24; Example 5). Clearly, cells derived from tumours are not untransformed, and the use of such transformed cells actually teaches away from the present invention. In addition, Evan indicates that the organisms from which the cells are derived include humans, simians, canines, rodents, and insects (page 24, line 30 - page 25, lines 1-6); there is no mention or suggestion of avian cells. Importantly, Givol does not remedy this deficiency. Givol relates to chicken embryo fibroblasts that are not immortalized (page 423, right column, last line - page

424, left column, lines 1-3). Accordingly, Evan and Givol, individually or combined, do not teach each and every element of the present invention, namely untransformed, immortalized avian cells.

Furthermore, one skilled in the art would not be motivated to combine these references to arrive at the present invention, which discloses untransformed and immortalized avian cells. Evan relates to immortalized, transformed cells, while Givol is specifically directed to cells that are not immortalized (page 423, right column, last line - page 424, left column, lines 1-3). There is simply nothing in the Evan reference to suggest the use of avian cells, nor is there any teaching in Givol to suggest immortalized cells. In fact, the very point of Givol's work is that the cells are not immortal and that the normal processes that control growth and division are not disturbed (page 423, right column, last line - page 424, left column, lines 1-3); therefore, these cells can be used to study bcl-2. This is in contrast to the immortalized cells of Evan (and the present invention), wherein growth control is indeed changed. In light of this, a skilled artisan would not be motivated to combine the cited references.

Finally, the Office Action contends that Givol provides the teaching of using avian cells in combination with Evan's teachings. However, there would not be a reasonable expectation of successfully arriving at the present invention using the teachings of Givol and Evan. One skilled in the art would recognize that it is not trivial to develop untransformed, immortalized avian cells. As indicated in the background of the present specification, the state of the art at the time the present application was filed does not provide any evidence that avian cells could be immortalized using viral oncogenes. Yet, the present inventors succeeded in developing untransformed, immortalized avian cell lines "contrary to all expectations" (page 3, lines 1-3). In fact, the present inventors produced untransformed, immortalized avian cells by integrating the SV40 T+t gene into the cells' genome. This gene inactivates both the p53 and RB product anti-oncogene proteins, which can induce transformation in cells. However, contrary to what is known in the art, the resulting avian cells were **untransformed** and **immortalized**. Neither Givol nor Evan teach or suggest an immortalized, untransformed cell line of any origin, let alone avian. Therefore, considering the known difficulty in producing the cells of the claimed invention, a skilled artisan would not reasonably expect to arrive at untransformed, immortalized avian cells by simply combining the teachings of Evan and Givol.

In short, the claimed invention is not obvious in view of Evan and Givol. The cited references do not teach or suggest every element and, in fact, teach away from the present invention. Further, Evan and Givol teach away from each other, which indicates that there is no motivation to even combine the references. Finally, there would not be a reasonable expectation of success, given the inherent difficulty in producing untransformed, immortalized avian cells. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

CONCLUSION

This application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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